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Documents Management Branch (HFA-305)
U. S. Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville MD 20852
U.S.A.

Dear Sir/ Madam,

Re: Documentation Submitted in Response to FDA Request for Data and Views: Notice of Eligibility for *Saccharomyces boulardii* (*S. boulardii*)
Docket Number 2004N-0346

In December 2003 Laboratoires BIOCOCODEX submitted a Time and Extent Application for *Saccharomyces boulardii* (*S. boulardii*) at a dose of one to two 250mg capsules per day for the symptomatic relief of diarrhea. In the Notice of Eligibility published on 11 August 2004 FDA called for submission of data and information to confirm if the condition can be generally recognised as safe and effective (GRAS/E) for its proposed OTC use, the deadline for submission of data, information and comments being November 22, 2004.

Accordingly BIOCOCODEX hereby submits comprehensive data to confirm that *S. boulardii* in the proposed condition should be considered GRAS/E for the intended OTC use. The data are contained within nine volumes of documentation, three copies of which are provided. Additionally Sections V.I. (Summary of Data and Views) and VII (proposed USP monograph) are provided as Word documents on CD Rom (3 CD copies provided).

The documentation included within this data package presents safety data arising from comprehensive human experience during marketing, further corroborated by safety data from 50 published clinical studies. Effectiveness is supported by eight controlled studies and 9 partially controlled or uncontrolled in the condition proposed for approval i.e. the treatment of acute diarrhea. Supportive data to confirm effectiveness are provided from 18 controlled studies and 12 partially controlled or uncontrolled studies in other forms of diarrhea e.g. travellers diarrhea, chronic diarrhea, prophylaxis of antibiotic diarrhea and AIDS associated diarrhea. While not in the condition proposed for OTC use, these supportive studies are of great relevance in providing additional confirmation of the efficacy of *S. boulardii* in the treatment of diarrhea of various etiologies.

Should you have any questions relating to the enclosed documentation please do not hesitate to contact me.

2004N-0346

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Thank you in advance for your consideration of the enclosed documentation and we look forward to receiving further communication from you in due course.

Yours faithfully



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cc Jean Vincent (Laboratoires BIOCDEX)
Michael Koenig (Division of Over the Counter Drug Products FDA)

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